

Environmental Protection Agency

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on the part of qualifying small manufacturers. Such manufacturers may choose to fulfill the standard requirements for their fuels and additives, individually or as a part of a group, rather than satisfying only the requirements specified in paragraphs (d)(2) and/or (d)(3) of this section. If a qualifying small manufacturer elects these special provisions rather than the standard requirements for a product, then EPA will generally assume that any additional information submitted by other manufacturers, for fuels and additives meeting the same grouping criteria (under § 79.56) as that of the small manufacturer's product, is pertinent to further testing and/or regulatory decisions that may affect the small manufacturer's product.

(6) In the case of an additive for which the manufacturer is not required to meet the requirements of Tier 2 pursuant to paragraph (d)(3) of this section:

(i) A fuel manufacturer which blends such an additive into fuel shall not be required to meet the requirements of Tier 2 with respect to such additive/fuel mixture.

(ii) An additive manufacturer which blends such an additive with one or more other registered additive products and/or with substances containing only carbon and/or hydrogen shall not be required to meet the requirements of Tier 2 with respect to such additive or additive blend.

(e) *Aftermarket Aerosol Additives.* (1) To obtain registration for an aftermarket aerosol fuel additive, the manufacturer shall provide existing information in the form of a literature search, a discussion of the potential exposure(s) to such product, and the basic registration data specified in § 79.59(b).

(2) The literature search shall include existing data on potential health and welfare effects due to exposure to the aerosol product itself and its raw (uncombusted) components. The analysis for potential exposures shall be based on the actual or anticipated production volume and market distribution of the particular aerosol product, and its estimated frequency of use. Other Tier 1 and Tier 2 requirements are not routinely required for aerosol products. EPA will review the sub-

mitted information and, at EPA's discretion, may require from the manufacturer further information and/or testing under Tier 3 on a case-by-case basis.

[59 FR 33093, June 27, 1994, as amended at 62 FR 12571, Mar. 17, 1997]

§ 79.59 Reporting requirements.

(a) *Timing.* (1) The manufacturer of each designated fuel or fuel additive shall submit to EPA the basic registration data detailed in paragraph (b) of this section. Forms for submitting this data may be obtained from EPA at the following address: Director, Field Operations and Support Division, 6406J—Fuel/Additives Registration, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

(i) For existing products (pursuant to § 79.51(c)(1)), manufacturers shall submit the basic registration data as specified in § 79.59(b) to EPA by November 28, 1994.

(ii) For registrable products (pursuant to § 79.51(c)(2)), manufacturers shall submit the basic registration data as specified in § 79.59(b) to apply for registration for such product.

(iii) For new products (pursuant to § 79.51(c)(3)), manufacturers are strongly encouraged to notify EPA of an intent to obtain product registration by submitting the basic registration data as specified in § 79.59(b) prior to starting Tiers 1 and 2.

(2) The information specified in paragraph (c) of this section shall be submitted to the address in paragraph (a)(1) of this section at the conclusion of activities performed in compliance with Tiers 1 and 2 under the provisions of §§ 79.52 and 79.53, according to the time constraints specified in § 79.51 (c) through (d).

(3) The information specified in paragraph (d) of this section shall be submitted to EPA at the address in paragraph (a)(1) of this section at the conclusion of activities performed in compliance with Tier 3 under the provisions of § 79.54.

(b) *Basic Registration Data.* Each manufacturer of a designated fuel or fuel additive shall submit the following data in regard to such fuel or fuel additive:

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(1) The information specified in § 79.11 or § 79.21. If such information has already been submitted to EPA in compliance with subpart B or C of this part, and if such previous information is accurate and up-to-date, the manufacturer need not resubmit this information.

(2) Annual production volume of the fuel or fuel additive product, in units of gallons per year if most commonly sold in liquid form or kilograms per year if most commonly sold in solid form. For fuels and fuel additives already in production, the most recent annual production volume and the volume projected to be produced in the third subsequent year shall be provided. For products not yet in production, the best estimate of expected annual volume during the third year of production shall be provided.

(3) *Market distribution of the product.* For fuels and bulk additives, this information shall be presented as the percent of total annual sales volume marketed in each Petroleum Administration for Defense District (PADD). The States comprising each PADD are listed in the following section. For aftermarket additives, the distribution data shall be presented as the percent of total annual sales volume marketed in each State. For a product not yet in production, the manufacturer shall present the distribution (by PADD or State, as applicable) projected to occur during the third year of production.

(i) The following States and jurisdictions are included in PADD I:

Connecticut	New Jersey
Delaware	New York
District of Columbia	North Carolina
Florida	Pennsylvania
Georgia	Rhode Island
Maine	South Carolina
Maryland	Vermont
Massachusetts	Virginia
New Hampshire	West Virginia

(ii) The following States are included in PADD II:

Illinois	Nebraska
Indiana	North Dakota
Iowa	Ohio
Kansas	Oklahoma
Kentucky	South Dakota
Michigan	Tennessee
Minnesota	Wisconsin
Missouri	

(iii) The following States are included in PADD III:

Alabama	Mississippi
Arkansas	New Mexico
Louisiana	Texas

(iv) The following States are included in PADD IV:

Colorado	Montana
Idaho	Utah
	Wyoming

(v) The following States are included in PADD V:

Alaska	Hawaii
Arizona	Nevada
California	Oregon
	Washington

(4) Any applicable information pursuant to the grouping provisions in § 79.56, as follows:

(i) If the manufacturer has enrolled or intends to enroll the product in a fuel/additive group, the relevant group and the person(s) or entity expected to submit information on behalf of the group must be identified.

(ii) If the manufacturer intends to rely on registration information previously submitted by another manufacturer (or group) for registration of other product(s) in the same fuel/additive group, then the original submitter and its product (or product group) shall be identified. In such cases, the manufacturer shall provide evidence that the original submitter has been notified of the use of its registration data and that the manufacturer has complied or intends to comply with the proportional reimbursement required under § 79.56(c) of this rule.

(5) Any applicable information pursuant to the special provisions in § 79.58, as follows:

(i) If the manufacturer claims applicability of the special provisions for re-labeled additives, pursuant to § 79.58(a), then the manufacturer and brand name of the original product shall be given.

(ii) If the manufacturer claims applicability of any small business provisions pursuant to § 79.58(d), the average of the manufacturer's total annual sales revenue for the previous three years shall be given.

(iii) If the manufacturer claims applicability of the special provisions for aerosol products, pursuant to § 79.58(e),

then the purpose and recommended frequency of use shall be given.

(c) *Tier 1 and Tier 2 Reports.* If the results of Tiers 1 and 2 are reported to EPA at the same time, then the report shall include the following documents in paragraphs (c)(1) through (7) of this section. If Tier 1 and Tier 2 results are submitted to EPA separately, then the separate Tier 1 report shall include only documents in paragraphs (c) (1) through (4), (c)(6), and associated appendices in paragraphs (c)(7) of this section, and the separate Tier 2 report shall include only documents in paragraphs (c)(1) through (3), (c)(5), (c)(6), and associated appendices in paragraph (c)(7) of this section. In addition, manufacturers complying with Tier 2 requirements according to one of the time schedules specified in § 79.51(c)(1)(ii)(B), § 79.51(c)(1)(vi)(B)(2), or § 79.51(c)(1)(vii)(B)(2) must submit evidence of a suitable arrangement for completion of Tier 2 (e.g., a copy of a signed contract with a qualified laboratory for applicable Tier 2 services) by the date specified in the applicable time schedule.

(1) *Cover page.* (i) Identification of test substance,

(ii) Name and address of the manufacturer of the test substance,

(iii) Name and phone number of a designated contact person,

(iv) Group information, if applicable, including:

(A) Group name or grouping criteria,

(B) Name and address of responsible organization or entity reporting for the group,

(C) Product trade name and manufacturer of each member fuel and additive to which the report pertains.

(2) *Executive Summary.* Text overview of the significant results and conclusions obtained as a result of completing the requirements of Tier 1 and/or Tier 2, including references if used to support such results and conclusions.

(3) *Test Substance Information.* Test substance description, including, as applicable,

(i) Base fuel parameter values (including types and concentrations of base fuel additives) or test fuel composition (if a fuel other than the base fuel is used in testing). These values

must be provided for each of the fuel parameters specified in § 79.55 for the applicable fuel family.

(ii) Test additive composition and concentration

(4) *Summary of Tier 1.* (i) *Literature Search.* Pursuant to § 79.52(d), the literature search shall include a text summary of the methods and results of the literature search, including the following:

(A) Identification of person(s) performing the literature search,

(B) Description of data sources accessed, search strategy used, search period, and terms included in literature search,

(C) Documentation of all unpublished in-house and other privately-conducted studies,

(D) Tables summarizing the protocols and results of all cited studies,

(E) Summary of significant results and conclusions with respect to the effects of the emissions of the subject fuel or fuel additive on the public health and welfare, including references if used to support such results and conclusions.

(F) Statement of the extent to which the literature search has produced adequate information comparable to that which would otherwise be obtained through the performance of applicable emission characterization requirements under § 79.52(b) and/or health effects testing requirements under § 79.53, including justifications and specific references.

(ii) *Emission Characterization.* Pursuant to § 79.52(b), the emission characterization shall include:

(A) Name, address, and telephone number of the laboratory performing the characterization,

(B) Name and description of analytic methods used for characterization.

(5) *Summary of Tier 2.* For each health effects test performed pursuant to the provisions of § 79.53, the Tier 2 summary shall contain the following information:

(i) Name, address, and telephone number of the testing facility,

(ii) Summary of procedures (including quality assurance, quality control and compliance with Good Laboratory Practice Standards as specified in

§ 79.60), findings, and conclusions, including references if used to support such results and conclusions.

(iii) Description of any problems and their resolution.

(6) *Conclusions*. The conclusions shall identify the need for further testing, if that need exists, or justify that current testing and/or available information is adequate for the tier(s) included in the report.

(7) *Appendices*. The appendices shall contain detailed documentation related to the summary information described in this section, including, at a minimum, the following five appendices:

(i) Literature search appendices shall contain:

(A) Copies of literature source outputs, including reference lists and associated abstracts from database searches, printed or on 3½ inch IBM-compatible computer diskettes;

(B) Summary tables organized by health or welfare endpoint and type of emission (e.g., combustion, evaporation, individual emission product), presenting in tabular form the following information at a minimum: number and species of test subjects, exposure concentrations/duration, positive (*i.e.*, abnormal) findings including numbers of test subjects involved, and bibliographic references;

(C) Complete documentation and/or reprints of articles for any previous study relied upon for satisfying emission characterization and/or Tier 2 test requirements; and

(D) Full reports for unpublished/in-house studies.

(ii) Emissions characterization appendices shall contain:

(A) Complete laboratory reports, including documentation of calibration and verification procedures;

(B) Documentation of the emissions generation procedures used; and

(C) Lists of speciated emission products and their emission rates reported in units of grams/mile.

(iii) [Reserved]

(iv) Tier 2 appendices shall contain, for each test performed:

(A) Complete protocol used;

(B) Documentation of emission generation procedures; and

(C) Complete laboratory report in compliance with the reporting standards in § 79.60, including detailed test results and conclusions, and descriptions of any problems encountered and their resolution.

(v) Laboratory certification/accreditation information, personnel credentials, and statements of compliance with the Good Laboratory Practices Standards specified in § 79.60 and the requirements in § 79.53(c)(1).

(d) *Tier 3 Report*. Subject to applicability as specified in § 79.54, each manufacturer of a designated fuel or fuel additive, or each group of such manufacturers pursuant to the provisions of § 79.56, shall submit the following information with respect to each Tier 3 test conducted for such fuels or fuel additives:

(1) The test objectives, including a summary of the reason(s) why such additional testing, beyond Tiers 1 and 2, was required;

(2) Name, address, and telephone number of each testing facility;

(3) Summary of test procedures, results and conclusions;

(4) Complete documentation of test protocols and emission generation procedures, complete laboratory reports in compliance with the reporting standards of § 79.60, detailed test results and conclusions, including references if used to support such results and conclusions, and descriptions of any problems encountered and their resolution; and

(5) Laboratory certification information, personnel credentials, and statements of compliance with the Good Laboratory Practices Standards specified in § 79.60.

(e) *Availability of Information*. (1) All health and safety test data and other information concerning health and welfare effects which is submitted by any manufacturer or group pursuant to §§ 79.52(c), 79.53, or 79.54, shall be considered to be public information and shall be made available to the public by EPA upon request. A reasonable fee may be charged by EPA for copying such materials. Any manufacturer or group who claims that any information concerning the composition of a fuel or

fuel additive product, or any other information, submitted under this subpart is confidential business information must state this claim in writing at the time of the submittal.

(2) To assert a business confidentiality claim concerning any information submitted under this subpart, the submitter must:

(i) Clearly mark the information as confidential at each location it appears in the submission; and

(ii) Submit with the information claimed as confidential a separate document setting forth the claim and listing each location at which the information appears in the submission.

(3) If any person subsequently requests access to information submitted under this subpart (other than health and safety test data and other information concerning health and welfare effects), and such information is subject to a claim of business confidentiality, the request and any subsequent disclosure shall be governed by the provisions of 40 CFR part 2.

[59 FR 33093, June 27, 1994, as amended at 62 FR 12572, 12576, Mar. 17, 1997]

§ 79.60 Good laboratory practices (GLP) standards for inhalation exposure health effects testing.

(a) *General Provisions*—(1) *Scope*. (i) This section prescribes good laboratory practices (GLPs) for conducting inhalation exposure studies relating to motor vehicle emissions health effects testing under this part. These directions are intended to ensure the quality and integrity of health effects data submitted pursuant to registration regulations issued under sections 211(b) or 211(e) of the Clean Air Act (CAA) (42 U.S.C. 7545).

(ii) This section applies to any study described by paragraph (a)(1)(i) of this section which any person conducts, initiates, or supports on or after May 27, 1994.

(iii) It is EPA's policy that all health effects data developed under sections 211(b) and (e) of CAA be in accordance with provisions of this section. If data are not developed in accordance with the provisions of this section, EPA may consider such data insufficient to evaluate the health effects of a motor vehicle's fuel or fuel additive emis-

sions, unless the submitter provides additional information demonstrating that the data are reliable and adequate and EPA determines that the data are sufficient.

(2) *Definitions*. As used in this section, the following terms shall have the meanings specified:

Batch means a specific quantity or lot of a test fuel, additive/base fuel mixture, or reference substance that has been characterized according to § 79.60(f)(1)(i).

CAA means the Clean Air Act.

Carrier means any material which is combined with engine/motor vehicle emissions or a reference substance for administration to a test system. "Carrier" includes, but is not limited to, clean, filtered air, water, feed, and nutrient media.

Control atmosphere means clean, filtered air which is administered to the test system in the course of a study for the purpose of establishing a basis for comparison with the test atmosphere for chemical or biological measurements.

Experimental start date means the first date the test atmosphere is applied to the test system.

Experimental termination date means the last date on which data are collected directly from the study.

Person includes an individual, partnership, corporation, association, scientific or academic establishment, government agency, or organizational unit thereof, and any other legal entity.

Quality assurance unit means any person or organizational element, except the study director, designated by testing facility management to perform the duties relating to quality assurance of the studies.

Raw data means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. "Raw data" may include